HIMA

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

July 19, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Docket No. 99D-0239

Dear Sir or Madam:

The Health Industry Manufacturers' Association ("HIMA") is pleased to provide comments on the Center for Devices and Radiological Health's ("CDRH's") implementation of section 404 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), specifically, section 562 of the Federal Food, Drug, and Cosmetic Act (the "Act"), and CDRH's draft guidance "Resolving Scientific Disputes Concerning the Regulation of Medical Devices."

HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world.

Section 562 requires the agency to establish, by regulation, a procedure by which a party before the agency may request review of a scientific controversy for which there was no specified review procedure in the Act or in regulations and obtain such review in a "timely manner." In promulgating an amendment to 21 CFR 10.75, which provides a general right to internal appeal of agency decisions, rather than establishing a specific procedure for resolution of scientific controversies, the agency ignored the law, which requires the creation of a separate specific procedure for independent and timely review of scientific disputes.

Section 562 specifically states that FDA "shall, by regulation, establish a procedure under which [parties] may request a review . . . ." of scientific controversies by a scientific advisory panel. Unquestionably the development of such a procedure should have been subject to notice and comment rulemaking. *See Newman v. Chater,* 87 F.3d 358 (9th Cir. 1996) ("When Congress says that the Commissioner shall prescribe circumstances by regulation, we see no reason why the Commissioner should be entitled to prescribe circumstances by other means."). The agency's

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decision to establish the specific procedure called for by section 562 of the Act in guidance documents, such as CDRH's draft guidance, is not in accordance with the statute and is therefore an illegal agency action under the Administrative Procedure Act (APA), 5 U.S.C. §706.

Additionally, CDRH's guidance effectively nullifies Congress's intent because it fails to provide review that is independent or timely. The guidance ignores the language of the statute by creating a requirement that the appeals process under 21 C.F.R. §10.75(b)(1) be exhausted in CDRH before consideration by an independent panel under 21 C.F.R. §10.75(b)(2) will be considered, and makes CDRH the arbiter of whether the review will be considered or granted. HIMA is very concerned that the guidance compromises procedural rights and undermines the independent review that Congress sought to achieve. HIMA is also concerned that both the specified and unspecified timeframes in the guidance will make timely review unachievable. Moreover, HIMA is dismayed that a right to review of scientific disputes has been eviscerated by procedures which change it into a matter of agency discretion.

Procedural Rights

Under the guidance, a request for dispute resolution must clear a substantial number of hurdles even to be considered, let alone to be granted. This is hardly the dispute resolution envisioned by Congress. CDRH retains the sole discretion to decide whether such review will be considered or permitted at every step of the way until the ultimate denial of the request.

First, the dispute must be about an agency "action" or "decision". This appears from the guidance to mean that parties will not be able to seek panel review of disputes that arise early on in the development and approval process. For example, in Scenario 4 in the guidance, it states that a dispute arising over PMA data requirements during a pre-submission IDE agreement conference, where the dispute has already been aired and not resolved at the Office level, would not be reviewable by the panel because "no formal FDA decision or action has been taken. Concerns instead could be directed to the CDRH director." Thus, review is denied because an unresolvable scientific dispute that did not result in a written agreement on clinical trial protocols purportedly is not an "action" or "decision". The statute refers only to a "scientific controversy" and not a "decision" or "action" that creates such a controversy. Nowhere is a formal agency action or decision required as a precursor to a request for advisory committee review. In fact, the intent of section 562 was that scientific disputes would receive "appropriate attention, and be resolved efficiently and quickly in order to expedite agency action on important matters." H.R. Rep. No. 105-310 at 73 (October 7, 1997). Thus, section 562 was intended to provide a way for resolution of disputes arising during the decision-making process to help facilitate agency action; it was not meant to be dependent upon a formal action or decision before invocation.

In addition, the guidance states that before a request for review will be considered for dispute resolution, the request must meet a large number of other criteria. Some of the criteria include whether other avenues for resolution, such as mediation, would be appropriate, and whether use of other less formal review mechanisms, such as supervisory review under 21 C.F.R. §10.75(b)(1), have been sufficiently utilized. Thus, litigation concepts of exhaustion of remedies and ripeness of review are built into the procedure laid out in the guidance--concepts which the statute does not require. The FDA should recognize that scientific controversies may arise, and often do, early in the premarket process and/or before formal decisions are made or actions taken, and provide the opportunity for such disputes to receive independent and timely review by an advisory panel.

Independence

Further, a decision by the CDRH Ombudsman that the threshold criteria are met only guarantees the request will be considered; whether a request for a dispute resolution panel is granted remains the decision of the CDRH Ombudsman in consultation with the Dispute Panel Chair and the Director of the CDRH division involved. Their consideration will include "whether mediation or Dispute Resolution Panel review is most appropriate, or whether some other dispute resolution process is preferable." This procedure places too many obstacles in the path of panel review and too much gatekeeping control in the hands of the very Center and Division involved in the dispute. Making CDRH the gatekeeper to panel review necessarily undermines the independence of the process. Simply put, the independence and credibility of the process requires persons other than those with a stake in the dispute to be decision-makers.

Under the guidance, a panel decision (statement of findings) is not binding. It is presented to the CDRH Director, who makes the final decision, including reversing or modifying the panel's decision. Making the CDRH Director the final arbiter of the resolution of the dispute essentially strips the process of any independence or meaning. The guidance assumes that prior to the request for dispute resolution, the dispute would be appealed up the chain in CDRH. Thus, the Director will have already reviewed the dispute and disagreed with the position of the requesting party. It seems unlikely that the Director will overrule the earlier adverse decision that led to the request for dispute resolution. If the CDRH Director is the final decision-maker, the panel's recommendation should stand unless it is contrary to law or would have a significant adverse impact on the public health. Only this type of approach preserves a modicum of independence in reviewing a scientific dispute within CDRH. Indeed, to the extent the Center Director reviews the controversy before a dispute resolution panel is convened, the panel's decision should be submitted to the Commissioner's Office and not to CDRH. Perhaps the FDA Ombudsman in that office is the best resort for evaluating a panel decision.

Timeliness of Review

Assuming the timeline laid out by CDRH in the guidance, if a request for panel review is granted, even without intervening mediation, it could take as long as 195 days from the date of the request for a decision to issue. With attempted mediation it could take at least 90 days more to obtain a panel decision. Further, parties are expected to appeal the dispute up through the Center before making a request for panel review, which could easily add months to the process. Clearly, the guidance does not provide for the "timely" review called for by the statute. To have any value, the process should take no longer than 60-90 days before a final decision is made.

Conclusion

In sum, FDA failed to follow the law and create through notice and comment rulemaking a procedure for dispute resolution of scientific controversies for which no other specific review mechanism is available under the law or regulations. Instead, FDA chose to create a dispute resolution procedure through guidance and in so doing set up a cumbersome and lengthy process that heavily favors CDRH over the party requesting Dispute Resolution Panel Review. The draft guidance lacks validity under the law and undermines the intent of section 562 to the point of nullifying the provision. HIMA requests that FDA repropose a dispute resolution procedure for scientific controversies through notice and comment rulemaking, and abandon its guidance document.

Attached are recommendations identifying elements HIMA believes will achieve Congress's intent in enacting section 404 of FDAMA (section 562 of the Act). We believe a final rule including these elements will benefit FDA and industry. HIMA appreciates the opportunity to comment on the draft guidance.

Sincerely,

Janet Trunzo

Janet Trunzo
Associate Vice-President
Technology and Regulatory Affairs

Dispute Resolution Recommendations

- Create a procedure to ensure the availability of individuals representing a wide array of subject matter expertise related to device design, manufacturing, and safety and effectiveness issues.[1] In determining the appropriateness of a review panel's composition, each panel member's knowledge of the device subject to the review and the disease states or conditions germane to the device must be evaluated to determine that the panel has sufficient expertise to resolve a controversy.

- Such a procedure should solicit nominees from the public and FDA for inclusion in a 515(g)(2)(B) advisory committee roster. Furthermore, the procedure should require prompt conflicts checks and periodic updating of conflicts information in order to ensure the conflict cleared status of a potential panel member. A procedure to ensure the availability of advisory committee members is critical to achieving the "timely" disposition of controversies required by section 562 of the Act.

- Limit the number of persons to participate on an advisory panel to three. It is important to simplify the creation of a review panel as much as possible.

- Include an executive secretary to assist the panel; however, the executive secretary should not be an employee of the Center involved in the controversy and preferably should be a representative of the Ombudsman's office.

- Specify a schedule for the review process. HIMA recommends that a panel be constituted within ten days of a written request for a panel review. The regulation should set forth the necessary content for such a request. Each panel member should be immediately provided, upon being selected for the panel, the written request for review. Within ten days of receipt by FDA, the agency should respond to the written request for a panel review stating its agreement or opposition with substantive points in the request for review. Within 20 days of the committee's receipt of FDA's response to the request for review, an informal hearing under Part 14 should be convened unless the parties to the controversy choose to have a committee decide the controversy on the papers. If a hearing occurs, the committee should provide the parties its written decision within 20 days of the hearing. If there is no hearing, the committee's decision should be required no later than 20 days after receipt of the agency's response to the request for hearing.

- Implement the committee's decision as binding, unless FDA determines that the weight of record evidence does not support the panel decision, or the agency determines that the committee applied incorrect legal standards or otherwise acted inconsistently with the law. If FDA rejects or modifies a panel decision for either of these reasons, the agency must be required to provide a full explanation of its action.

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[1]Because section 562 also covers drugs and biologics, analogous requirements to those suggested for devices should be included in the proposed regulation.